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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|---|-----------------|----------------------|-------------------------|------------------|--|
| 09/886,899 | 06/21/2001 | Robin Lovell-Badge | 18396/2032 | 6109 | |
| 29933 | 7590 02/10/2004 | | EXAM | EXAMINER | |
| PALMER & | DODGE, LLP | | FREDMAN, JEFFREY NORMAN | | |
| KATHLEEN M. WILLIAMS 111 HUNTINGTON AVENUE BOSTON, MA 02199 | | | ART UNIT | PAPER NUMBER | |
| | | | 1634 | | |

DATE MAILED: 02/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | |
|---|---------------------------------|---|--|--|--|
| Advisory Action | 09/886,899 | LOVELL-BADGE ET AL. | | | |
| ravisory rieden | Examiner | Art Unit | | | |
| | Jeffrey Fredman | 1634 | | | |
| The MAILING DATE of this communication app | ars on the cover sheet with th | orrespondence address | | | |
| THE REPLY FILED 23 January 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. | | | | | |
| PERIOD FOR REPLY [check either a) or b)] | | | | | |
| a) The period for reply expires 3 months from the mailing date of the final rejection. b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | |
| 1. A Notice of Appeal was filed on Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal. | | | | | |
| 2. The proposed amendment(s) will not be entered because: | | | | | |
| (a) Method they raise new issues that would require further consideration and/or search (see NOTE below); | | | | | |
| (b) ☑ they raise the issue of new matter (see Note below); | | | | | |
| (c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or | | | | | |
| (d) they present additional claims without canceling a corresponding number of finally rejected claims. | | | | | |
| NOTE: See Continuation Sheet. | | | | | |
| 3. Applicant's reply has overcome the following rejection. | | | | | |
| 4. Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s). | | | | | |
| 5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: <u>See Continuation Sheet</u> . | | | | | |
| 6. The affidavit or exhibit will NOT be considered becaraised by the Examiner in the final rejection. | cause it is not directed SOLELY | to issues which were newly | | | |
| 7. For purposes of Appeal, the proposed amendment explanation of how the new or amended claims we | | | | | |
| The status of the claim(s) is (or will be) as follows: | • | | | | |
| Claim(s) allowed: | | | | | |
| Claim(s) objected to: | | | | | |
| Claim(s) rejected: <u>1-8,16 and 17</u> . | | | | | |
| Claim(s) withdrawn from consideration: 9-15. | | | | | |
| 8. ☐ The drawing correction filed on is a) ☐ approved or b) ☐ disapproved by the Examiner. | | | | | |
| 9. Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s) | | | | | |
| 10. Other: | | Jeffrey Fredman Primary Examiner Art Unit: 1634 | | | |

Continuation Sh t (PTOL-303) 009/886,899

Continuation of 2. NOTE: The amendment inserts Genbank accession numbers into the claims in order to describe the DNA sequences. However, Genbank accession numbers were not previously present and raise significant new issues regarding new search, new issues and new matter. For example, Y13436, the Sox-1 gene, has a comment that "On Jan 8, 1999, this sequence version replaced gi:2230882". So when Applicant refers to Y13436, which sequence version is being referred to. For example the current sequence version has 4091 nucleotides while the previous version only had 1542 nucleotides. So the sequences are clearly different. It may be new matter to refer to such a version, when the changes were not contemplated by Applicant. Further, this raises issues of definiteness of the claims since it is not necessarily clear what sequence is Y13436, the current version (as of February 5, 2004), a previous version, or some newer version which may be inputted tomorrow or at some later date. Therefore the claims will not be entered as raising new issues of new matter and indefiniteness, as well as potentially requiring further search.

Continuation of 5. does NOT place the application in condition for allowance because: Applicant argues that the claims overcome the 112 first because of the limitation to specific accession numbers. As noted above, this limitation is not entered for the reasons given and those arguments are therefore moot. However, the arguments with regard to the remaining issues were substantially addressed in the final rejection. The argument that "any cell" or "any organism" is not unpredictable when only a single example in a single organism is given, and no evidence of the effect of these genes on a variety of cell types in a variety of organisms is given is not found persuasive and this element of the rejection is maintained.